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UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

JANSSEN PHARMACEUTICALS, INC. and GRÜNENTHAL GMBH, Plaintiffs, v. ROXANE LABORATORIES, INC., Defendant.	**Case No:** **COMPLAINT**

In this patent infringement action, Plaintiffs Janssen Pharmaceuticals, Inc. ("Janssen") and Grünenthal GmbH ("Grünenthal"), for their complaint against Defendant Roxane

Laboratories, Inc. ("Roxane"), allege as follows:

SUBJECT MATTER JURISDICTION

1. This action for patent infringement arises under 35 U.S.C. § 1 *et seq.* generally and 35 U.S.C. § 271(e)(2) specifically.

2. This Court has subject matter jurisdiction over this dispute pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

PERSONAL JURISDICTION

3. This Court has personal jurisdiction over Roxane by virtue of the fact that, *inter alia*, on information and belief Roxane is incorporated under the laws of the State of Nevada and is therefore a resident of Nevada. Additionally, on information and belief, Roxane has designated as an agent for service of process The Corporation Trust Company of Nevada, 311 South Division Street, Carson City, Nevada 89703.

VENUE

4. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

NATURE OF THE ACTION

5. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, in response to the submission of an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of NUCYNTA® prior to the expiration of U.S. Reissue Patent No. 39,593 E ("the RE593 Patent") and U.S. Patent No. 7,994,364 B2 ("the '364 Patent").

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THE PARTIES

6. Plaintiff Grünenthal is a corporation organized and existing under the laws of Germany, having an address at Zieglerstrasse 6, 52078 Aachen, Germany. Grünenthal owns the RE593 and '364 Patents.

7. Plaintiff Janssen is a Pennsylvania corporation, having its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560. As discussed below, Janssen is an exclusive licensee of the RE593 and '364 Patents.

8. Janssen holds FDA-approved New Drug Application ("NDA") No. 022304.

9. Janssen manufactures and markets the drug covered by NDA No. 022304 ("NUCYNTA" or the "NUCYNTA drug product") in the United States. The active ingredient of NUCYNTA is tapentadol hydrochloride. The drug is marketed under the registered trade name NUCYNTA®. Under NDA 022304, NUCYNTA is marketed in 50, 75 and 100 mg tablets.

10. NUCYNTA is approved by the FDA for the management of moderate to severe acute pain in adults.

11. On information and belief, Defendant Roxane is a corporation existing under the laws of the State of Nevada, having a place of business at 1809 Wilson Road, Columbus, OH 43228. Roxane is registered to do business in Nevada as a domestic corporation under Business I.D. No. NV20051224750.

THE PATENTS-IN-SUIT

RE593 Patent

12. The RE593 Patent, entitled "1-PHENYL-3-DIMETHYLAMINOPROPANE COMPOUNDS WITH A PHARMACOLOGICAL EFFECTS," was duly and legally issued on

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April 24, 2007, naming Helmut Buschmann, Elmar Friderichs, and Wolfgang Strassburger as the inventors. A copy of the RE593 Patent is attached hereto as Exhibit 1.

13. The RE593 Patent is a reissue of U.S. Patent No. 6,248,737, issued on June 19, 2001.

14. Plaintiff Grünenthal lawfully owns all right, title and interest in the RE593 Patent, including the right to sue and to recover for past infringement thereof.

15. Plaintiff Janssen is an exclusive licensee of the RE593 Patent, holding an exclusive license to import, market, distribute, promote, offer to sell or sell pharmaceutical formulations containing tapentadol for human use in the field of pain within the United States, with a right to enforce the RE593 Patent.

16. The FDA issues a publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book").

17. In accordance with 21 U.S.C. § 355(b)(1), the RE593 Patent is listed in the Orange Book in connection with NDA No. 022304 as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" NUCYNTA.

The '364 Patent

18. The '364 Patent, entitled "CRYSTALLINE FORMS OF (-)-(1R,2R)-3-(3-DIMETHYLAMINO-1-ETHYL-2-METHYLPROPYL)-PHENOL HYDROCHLORIDE," was duly and legally issued on August 9, 2011, naming Andreas Fischer, Helmut Buschmann, Michael Gruss, and Dagmar Lischke as the inventors. A copy of the '364 Patent is attached hereto as Exhibit 2.

19. Plaintiff Grünenthal lawfully owns all right, title and interest in the '364 Patent, including the right to sue and to recover for past infringement thereof.

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20. Plaintiff Janssen is an exclusive licensee of the '364 Patent, holding an exclusive license to import, market, distribute, promote, offer to sell or sell pharmaceutical formulations containing tapentadol for human use in the field of pain within the United States, with a right to enforce the '364 Patent.

21. In accordance with 21 U.S.C. § 355(b)(1), the '364 Patent is listed in the Orange Book in connection with NDA No. 022304 as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" NUCYNTA.

THE DEFENDANT'S ANDA

22. On information and belief, Roxane submitted ANDA No. 205057 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking FDA approval to engage in the commercial manufacture, use, importation, offer for sale, and sale of generic 50 mg, 75 mg, and 100 mg tapentadol hydrochloride tablets (the "ANDA No. 205057 Products").

23. On information and belief, Roxane's ANDA No. 205057 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification") alleging that the RE593 and '364 Patents are "invalid, not infringed, and/or unenforceable."

24. On information and belief, Roxane is the owner of ANDA No. 205057.

25. On information and belief, if ANDA No. 205057 is approved by the FDA before the expiration of the RE593 and '364 Patents, Roxane will begin manufacturing, using, importing, offering for sale, and/or selling the ANDA No. 205057 Products, despite the patents.

26. On information and belief, if ANDA No. 205057 is approved by the FDA, Roxane will begin marketing the ANDA No. 205057 Products for the management of moderate

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to severe acute pain in adults, and doctors and patients will use each of the dosage strengths of the ANDA No. 205057 Products for the indication marketed by Roxane.

27. Roxane has correctly represented that the Reference Listed Drug of ANDA No. 205057 is NUCYNTA.

28. Pursuant to FDA regulation 21 C.F.R. § 314.94, in order to secure FDA approval, each of the ANDA No. 205057 Products' dosage strengths must have the same strength as one of the approved dosages for NUCYNTA. In addition, the ANDA No. 205057 Products must be bioequivalent to NUCYNTA.

29. On or about October 8, 2013, Plaintiff Janssen received a letter dated October 3, 2013 (the "October 3, 2013 notice letter"), constituting the notice of ANDA No. 205057, including the Paragraph IV certification, required by 21 U.S.C. § 355(j)(2)(B)(i)-(ii). On or about October 21, 2013, Plaintiff Grünenthal received a letter dated October 3, 2013, constituting notice of ANDA No. 205057, including the Paragraph IV certification, required by 21 U.S.C. § 355(j)(2)(B)(i)-(ii). That notice demonstrates an actual and justiciable controversy. The Paragraph IV certification alleged that the claims of the RE593 and '364 Patents are "invalid, not infringed, and/or unenforceable."

30. By the filing of this Complaint, an action was commenced within forty-five days of the date of receipt of the October 3, 2013 notice letter of ANDA No. 205057.

31. On information and belief, Roxane was aware of the RE593 and '364 Patents when ANDA No. 205057 was submitted to the FDA, containing the above-described Paragraph IV certification concerning these specific patents.

32. Pursuant to 35 U.S.C. § 271(e)(2)(A), the submission of ANDA No. 205057 with a Paragraph IV certification seeking approval to market the ANDA No. 205057 Products is an act of infringement by Roxane of one or more claims of the RE593 and '364 Patents. This

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infringement entitles Plaintiffs to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 205057 be a date which is not earlier than the expiration date of the last expiring of the RE593 and '364 Patents, including any extensions of that date.

COUNT I: INFRINGEMENT OF THE RE593 PATENT

33. Plaintiffs incorporate and reallege Paragraphs 1-17 and 22-32 above.

34. The submission of ANDA No. 205057 with a Paragraph IV certification regarding the RE593 Patent was an act of infringement by Roxane of one or more claims of the RE593 Patent under 35 U.S.C. § 271(e)(2)(A).

35. On information and belief, the ANDA No. 205057 Products are covered by one or more claims of the RE593 Patent.

36. On information and belief, Roxane's commercial importation, manufacture, use, sale, and/or offer for sale of the ANDA No. 205057 Products before the expiration of the RE593 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the RE593 Patent.

37. On information and belief, the use of Roxane's ANDA No. 205057 Products in accordance with and as directed by Roxane's proposed labeling will infringe one or more claims of the RE593 Patent.

38. On information and belief, by seeking approval to distribute the ANDA No. 205057 Products with their proposed labeling, Roxane intends to cause others, specifically, for example, medical professionals and patients, to perform acts that Roxane knows will infringe one or more claims of the RE593 Patent.

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39. On information and belief, unless enjoined by this Court, Roxane plans and intends to, and will, actively induce infringement of one or more claims of the RE593 Patent immediately following approval of ANDA No. 205057.

40. On information and belief, unless enjoined by this Court, Roxane plans and intends to, and will, contribute to the infringement of one or more claims of the RE593 Patent immediately following approval of ANDA No. 205057.

41. On information and belief, Roxane knows that its ANDA No. 205057 Products and their proposed labeling are especially made or adapted for use in infringing one or more claims of the RE593, and that Roxane's ANDA No. 205057 Products and their proposed labeling are not suitable for any substantial noninfringing use.

42. On information and belief, Roxane has been aware of the existence of the RE593 Patent since before the submission of ANDA No. 205057.

43. On information and belief, Roxane has no reasonable basis for believing that its ANDA No. 205057 Products will not infringe one or more valid claims of the RE593 Patent and no reasonable basis for believing that the infringed claims are invalid.

44. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

45. On information and belief, unless enjoined by this Court, Roxane plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the ANDA No. 205057 Products with their proposed labeling immediately following approval of ANDA No. 205057.

46. The acts of infringement by Roxane set forth above will cause Plaintiffs Janssen and Grünenthal irreparable harm for which they have no adequate remedy at law, and those acts will continue unless enjoined by this Court.

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47. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Roxane's ANDA No. 205057 to be a date which is not any earlier than the expiration date of the RE593 Patent, including any extensions of that date.

COUNT II: INFRINGEMENT OF THE '364 PATENT

48. Plaintiffs incorporate and reallege Paragraphs 1-11 and 18-32 above.

49. The submission of ANDA No. 205057 with a Paragraph IV certification regarding the '364 Patent was an act of infringement by Roxane of one or more claims of the '364 Patent under 35 U.S.C. § 271(e)(2)(A).

50. On information and belief, the ANDA No. 205057 Products are covered by one or more claims of the '364 Patent.

51. On information and belief, Roxane's commercial importation, manufacture, use, sale, and/or offer for sale of the ANDA No. 205057 Products before the expiration of the '364 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '364 Patent.

52. On information and belief, the use of Roxane's ANDA No. 205057 Products in accordance with and as directed by Roxane's proposed labeling will infringe one or more claims of the '364 Patent.

53. On information and belief, by seeking approval to distribute the ANDA No. 205057 Products with their proposed labeling, Roxane intends to cause others, specifically, for example, medical professionals and patients, to perform acts that Roxane knows will infringe one or more claims of the '364 Patent.

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54. On information and belief, unless enjoined by this Court, Roxane plans and intends to, and will, actively induce infringement of one or more claims of the '364 Patent immediately following approval of ANDA No. 205057.

55. On information and belief, unless enjoined by this Court, Roxane plans and intends to, and will, contribute to the infringement of one or more claims of the '364 Patent immediately following approval of ANDA No. 205057.

56. On information and belief, Roxane knows that its ANDA No. 205057 Products and their proposed labeling are especially made or adapted for use in infringing one or more claims of the '364 Patent, and that Roxane's ANDA No. 205057 Products and their proposed labeling are not suitable for any substantial noninfringing use.

57. On information and belief, Roxane has been aware of the existence of the '364 Patent since before the submission of ANDA No. 205057.

58. On information and belief, Roxane has no reasonable basis for believing that its ANDA No. 205057 Products will not infringe one or more valid claims of the '364 Patent and no reasonable basis for believing that the infringed claims are invalid.

59. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

60. On information and belief, unless enjoined by this Court, Roxane plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the ANDA No. 205057 Products with their proposed labeling immediately following approval of ANDA No. 205057.

61. The acts of infringement by Roxane set forth above will cause Plaintiffs Janssen and Grünenthal irreparable harm for which they have no adequate remedy at law, and those acts will continue unless enjoined by this Court.

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62. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Roxane's ANDA No. 205057 to be a date which is not any earlier than the expiration date of the '364 Patent, including any extensions of that date.

RELIEF SOUGHT

WHEREFORE, Plaintiffs respectfully request the following relief:

A. Judgment in favor of Plaintiffs and against Defendant;

B. Judgment that the RE593 and '364 Patents have not been proven invalid and unenforceable;

C. Judgment that Roxane has infringed, literally or by the doctrine of equivalents, the RE593 and '364 Patents by the submission of ANDA No. 205057, and that the commercial importation, sale, offer for sale, use, and/or manufacture of the ANDA No. 205057 Products, in the United States, would infringe, induce infringement of, and/or contribute to the infringement of the RE593 and '364 Patents;

D. Judgment, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of approval of ANDA No. 205057 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), shall be a date not earlier than the date of expiration of the latest of the RE593 and '364 Patents plus any additional periods of exclusivity;

E. A preliminary and permanent injunction, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., enjoining Roxane, and its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, from any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any ANDA No. 205057

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Product, and any product that is similar to or only colorably different from those products, before the date of expiration of the latest of the RE593 and '364 Patents and any additional periods of exclusivity;

F. A declaration that this is an exceptional case and an award to Plaintiffs Janssen and Grünenthal of their reasonable attorneys' fees and expenses, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

G. Damages or other monetary relief, including prejudgment interest, if Roxane engages in the commercial manufacture, use, offering to sell, sale, marketing, distribution, or importation of ANDA No. 205057 Products, or any other products that infringe the RE593 or '364 Patents, or the inducement of or contribution to the foregoing, prior to the expiration of the RE593 and/or '364 Patents;

H. An award of pre-judgment and post-judgment interest on each and every award;

I. An award of Plaintiffs' taxable costs in bringing and prosecuting this action; and

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J. Such other and further relief to Plaintiffs Janssen and Grünenthal as this Court may deem just and proper.

Respectfully submitted,

DATED this 15h day of November 2013.

GORDON SILVER

By: /s/ Molly M. Rezac

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